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The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 09-037-RBK-JS

Dear Judge Schneider:

Pursuant to the Court's November 30, 2012 Order (D.I. 572), Plaintiff Sciele Pharma, Inc., n/k/a Shionogi Inc. ("Shionogi") submits this letter brief concerning Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc.'s ("Lupin") refusal to produce relevant settlement and licensing documents.

I. Lupin Refuses to Produce Highly Relevant Documents Concerning Licensing Agreements Related to the Patented Technology

Shionogi claims damages resulting from Lupin's sale of infringing copies of Shionogi's Fortamet®, an extended-release metformin HCl tablet indicated for the treatment of diabetes. One of the damages issues in this case is Lupin's contention that the appropriate measure of Shionogi's damages is a reasonable royalty. The determination of a reasonable royalty is informed by the so-called *Georgia-Pacific* factors, of which two are particularly relevant to the instant dispute. Factor 2 calls for a consideration of "the rates paid by the licensee for the use of other patents ***comparable*** to the patent in suit" and factor 12 concerns the "portion of the profit or of the selling price that may be customary in the particular business or in ***comparable businesses*** to allow for the use of the invention or analogous inventions." *See Georgia-Pac.*

Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) *modified sub nom. Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971) (emphasis added).

Accordingly, on October 5, 2012, Shionogi served two document requests concerning these factors to Lupin. In particular, the requests called for licensing agreements that Lupin entered into concerning patents Shionogi believes may be comparable to the patents in suit and/or comparable businesses and analogous inventions. Specifically, Shionogi's requests were directed to the following types of agreements that Shionogi believes are reasonably calculated to lead to the discovery of admissible evidence regarding the *Georgia-Pacific* analysis:

1. A licensing agreement between Depomed Inc. ("Depomed") and Lupin involving Glumetza®, which, like Fortamet®, is an extended-release metformin HCl tablet indicated for the treatment of diabetes;

2. Biguanides, which is in the class of compounds that includes metformin, the active ingredient in Fortamet®;

3. Other pharmaceutical products indicated for the treatment of diabetes;

4. Pharmaceutical products with extended-release characteristics; and

5. Communications concerning or associated with these agreements, including negotiations, forecasts, and analyses.

See Ex. A, Shionogi's Fourth Set of Requests for the Production of Documents and Things, Nos. 88 and 89. On November 7, Lupin responded by objecting that these requests were burdensome and overly broad. During a November 20 meet and confer, Lupin again refused to produce the requested documents, asserting that the requested discovery concerned different products, patents, and litigations.

At the November 29 status conference, the Court heard oral argument on this dispute and ordered additional briefing. D.I. 572. Shionogi and Lupin then held a subsequent meet and confer during which Shionogi offered to narrow its requests for the fourth category of documents to agreements involving *patents* concerning pharmaceutical products with extended-release characteristics. Lupin, however, rejected that proposal and refused to offer a counterproposal. Lupin even refused to produce the Depomed-Lupin agreement, which concerns an extended-release metformin HCL tablet. Finally, in a continued effort to narrow the dispute, Shionogi asked Lupin to identify the number of agreements encompassed by Shionogi's requests in an effort to assess Lupin's overbreadth and burden objections. Lupin refused to answer.

As discussed below, Shionogi's document requests are not overbroad or unduly burdensome. Rather, they are directed at obtaining highly relevant information necessary for Shionogi to develop its damages case.

II. *Document Request No. 88:* Licensing Agreements Concerning the Patented Technology

Lupin objects to producing the requested licensing agreements for two primary reasons: (1) licensing agreements that stem from litigation are allegedly inadmissible under Rules 403 and 408 of the Federal Rules of Evidence and are therefore shielded from discovery; and (2) licensing agreements involving other products, patents, or litigations should not be discoverable. Both arguments are without merit.

A. Relevance, Not Admissibility, Determines Whether the Agreements are Discoverable

Lupin raises a variation of the admissibility argument the Court rejected when it ordered production of the rescinded agreement between Lupin and Mylan relating to Lupin's ANDA for a generic copy of Fortamet® ("the Lupin-Mylan agreement"). There, Mylan contended the agreement was inadmissible under Rule 408 of the Federal Rules of Evidence and was therefore not discoverable. In rejecting that argument, the Court explained that Mylan's reliance on Rule 408 was "misguided," because that rule concerns *admissibility* of evidence at trial, not *discoverability*. *See* D.I. 545 at 14.

Lupin's additional citation to Fed. R. Evid. 403 is equally misguided—Rule 403 also addresses admissibility, not discoverability. *See, e.g., Levick v. Maimonides Med. Ctr.*, C.A. No. 08 CV 03814 NG, 2011 WL 1673782, at *1 (E.D.N.Y. May 3, 2011) ("The plaintiff's first argument applies the incorrect standard to disputes over discovery. While Rules 403 and 408 may limit the admissibility of the settlement agreement at trial, this does not determine its discoverability."); *Sapko v. Ringgold Area Sch. Dist.*, C.A. No. 06-893, 2007 WL 3023956, at *1 (W.D. Pa. Oct. 12, 2007) ("Rule 403 addresses admissibility . . . and the standards governing discovery address different concerns and are more lenient."). Indeed, the Federal Circuit has held that patent licenses entered into in settlement of litigation can be the most relevant evidence in appropriate cases. *See ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869-872 (Fed. Cir. 2010). They must, therefore, be discoverable.

The Requested Agreements are Likely to Lead to the Discovery of Admissible Evidence Relevant to the Reasonable Royalty Determination

There can be no real dispute that licensing agreements are relevant to a reasonable royalty calculation, even where the agreements arise from other litigations and involve other similar patents and products. Indeed, as stated above, at least two of the *Georgia-Pacific* factors used to calculate a reasonable royalty expressly contemplate considering licenses for other patents and inventions:

- *Factor No. 2*: The rates paid by the *licensee* for the use of *other patents comparable to the patent in suit*.

- *Factor No. 12*: The portion of the profit or of the selling price that may be customary in the particular business or *in comparable businesses* to allow for the use of the invention *or analogous inventions.*

See Georgia-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) *modified sub nom. Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971) (emphasis added).

Thus, as the Court has already noted, Federal Circuit "cases appropriately recognize that settlement agreements can be pertinent to the issue of reasonable royalties." D.I. 545 at 14-15 (quoting *In re MSTG, Inc.*, 675 F.3d 1337, 1348 (Fed. Cir. 2012)). Federal Circuit precedent also recognizes that agreements involving other products or patents are relevant to a reasonable royalty determination, even if those agreements arise from a different litigation, where the agreements are "sufficiently comparable to the hypothetical license at issue in suit." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009). *See generally ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869-872 (Fed. Cir. 2010). Indeed, patent licenses between an innovator pharmaceutical company such as Shionogi, and a generic copyist concerning the generic copy, are rare outside the sphere of litigation or threatened litigation. Were such license agreements excluded from discovery in litigation between innovators and generics, there would be virtually no evidence on which to rely for these two *Georgia-Pacific* factors.

Despite this precedent, Lupin argues that the requested agreements are not discoverable because one or more of the agreements concern a different patent, product, or litigation. The flaw in that reasoning is readily apparent: under Lupin's view, "comparable" means "exactly the same." As noted above, however, that is not the law. Moreover, while there may ultimately prove to be disputes between experts as to whether a particular agreement involves comparable patents, a comparable business, or an analogous invention, such disputes are not resolved at the discovery stage. Rather, they go to the weight of the evidence and the credibility of the experts' opinions. Nor has Shionogi requested every license agreement into which Lupin has ever entered. Instead, Shionogi tailored its requests to technology and businesses similar to those at issue in this litigation and those tailored requests are "reasonably calculated to lead to the discovery of admissible evidence." Clearly, not every document requested by Shionogi must be admissible. However, Shionogi, and its expert, are entitled to examine this tailored universe to determine which licenses they will rely on as relevant to *Georgia-Pacific* factors 2 and 12. And Shionogi is entitled to examine Lupin's expert as to why he or she either did not consider, or excluded, a particular agreement from his or her analysis.

Moreover, Lupin's position again improperly conflates the standards of admissibility and discoverability. Rule 26 of the Federal Rules of Civil Procedure governs the scope of discovery and permits "discovery regarding any nonprivileged matter that is *relevant* to any party's claim or defense." Fed. R. Civ. P. 26(b)(1) (emphasis added). This is true even if the matter is not admissible at trial. *See id.* In keeping with the broad and liberal policy underlying discovery, "[r]elevance under Rule 26(b)(1) is construed more broadly for discovery than for trial." *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1024 (Fed. Cir. 1986). Accordingly, courts have broadly interpreted "comparability" for purposes of discovery. *See e.g., Trading Techs.*

Int'l, Inc. v. eSpeed, Inc., 04 C 5312, 2007 WL 704525 (N.D. Ill. Mar. 1, 2007) ("While *Georgia-Pacific* does indicate that the patents to which we may look to determine a reasonable royalty rate must be 'comparable,' courts have often interpreted this factor broadly."). This is for good reason—a party cannot determine whether a license is "comparable" for the purposes of trial (as opposed to discovery) if it is not privy to the specific terms and conditions of that license.

At bottom, Lupin will have a chance to contest the weight and admissibility of the agreements at a later date, but those issues are not yet before the Court. As one district court has explained:

> If, as defendants contend, the patents at issue are not comparable and will not give any indication of what the patents-in-suit would be worth, they will not carry weight in the final determination. But defendants are getting ahead of themselves. We are currently dealing with discovery, not the admission or weight of any evidence, and plaintiff has failed to point us to any court that has limited such discovery.

Trading Techs. Int'l, Inc., 2007 WL 704525, at *2 (internal citation omitted).

As explained in the accompanying Declaration of Christopher P. Gerardi (Ex. B), each of the four categories of requested information satisfies the discovery standard:

- *The Depomed-Lupin Agreement*: This agreement concerns similar technology (both Glumetza® and Fortamet® are extended-release metformin HCl tablets used for treating diabetes), similar circumstances (negotiations between an innovator and a generic company in a two-player market for rights to the patents in suit), and similar patents (the patents at issue all involve extended-release drug formulations). *See* Gerardi Decl., ¶ 5. These similarities show the patents and businesses are more than sufficiently "comparable" for the purposes of discovery. *See ResQNet.com, Inc.*, 594 F.3d 860 at 873 (noting that courts should consider the "technological and economic differences" between the agreement under consideration and the patent in suit).

- *Biguanides*: The active ingredient in Fortamet®, metformin, is a biguanide. Agreements between Lupin and third parties concerning other biguanides are likely to involve comparable businesses (similar pharmaceutical products) as well as comparable or analogous patents. They are also likely to shed light on the value Lupin has placed on comparable compounds and, therefore, on Fortamet®. These agreements will also provide insight on how Lupin might structure a Fortamet® license agreement. *See* Gerardi Decl., ¶ 5. Moreover, the patents in suit include claims directed to biguanides, directly tying such license agreements to the patented technology. *See, e.g.*, U.S. Patent No. 6,099,859, at cl. 2 ("A controlled release pharmaceutical tablet as defined in claim 1 wherein the antihyperglycemic drug is a *biguanide*." (emphasis added)); U.S. Patent No. 6,866,866, at cl. 1 ("A controlled release oral dosage form . . . comprising an effective dose of *metformin* . . . ." (emphasis added)); *see also* Gerardi Decl., ¶ 5. Agreements involving other biguanides would also reflect any customary portion of the profit or selling price specific to biguanides. *See* Gerardi Decl., ¶ 5.

- *Patents Concerning Extended-Release Pharmaceuticals Technology:* The patents in suit concern extended-release pharmaceutical technology. Therefore, other extended-release technology patents are likely to involve comparable technology and comparable businesses—other extended-release pharmaceutical products. Accordingly, licenses to such patents are discoverable. They are likely to shed light on the value Lupin places on such patent rights. *See* Gerardi Decl., ¶5. Similarly, such agreements are likely to reflect any customary portion of the profit or selling price specific to extended-release pharmaceuticals. *Id.*

- *Pharmaceutical Products Indicated for the Treatment of Diabetes*: Agreements between Lupin and others involving treatment of diabetes are also probative of how Lupin may value and structure a royalty agreement for the patents in suit. As noted above, Fortamet® is indicated for the treatment of diabetes, and the patents in suit concern controlled-release compositions used to treat diabetes. Thus, Lupin's agreements concerning other diabetes drugs are likely to reflect other comparable businesses and patents, and would be appropriate to consider. *See* Gerardi Decl., ¶ 5. They would also reflect any customary portion of the profit or selling price specific to diabetes drugs. *Id.*

III. *Document Request No. 89:* Underlying Documents and Communications are Relevant to the Determination of a Reasonable Royalty

The documents and communications, including negotiations, forecasts, and analyses, that Shionogi seeks are relevant to the reasonable royalty determination for at least the following reasons. First, they are informative on the technological and economic comparability of other agreements. Second, they are relevant to how Lupin values comparable patents and technologies. Third, to the extent the agreements are litigation-related, *e.g.*, the Depomed-Lupin agreement, they may show whether these agreements accurately reflect the value of the patents and technologies, or whether they were strongly influenced by a desire to avoid or to terminate litigation. Finally, they can explain the structure of comparable agreements, including whether license payments are in the form of an on-going royalty or a lump sum, and an appropriate royalty base.

In *ResQNet*, the Federal Circuit advised the district court on remand to consider "the panoply of events and facts that occurred [after the hypothetical negotiation] and that could not have been known to or predicted by the hypothesized negotiators." *ResQNet*, 594 F.3d at 872 (internal citation omitted). Following *ResQNet*, courts have routinely compelled production of the categories of documents Shionogi is seeking. For example, in *Tyco Healthcare Group LP v. E-Z-EM, Inc.*, the court compelled the production of settlement negotiation documents relating to a different patent in a different litigation on the ground that "the parties are entitled to show whether and to what extent the rate from a prior license agreement is the result of a compromise or reflects a desire to avoid litigation." C.A. No. 2:07 CV 262, 2010 WL 774878, at *2 (E.D.Tex. Mar. 2, 2010). That same rationale applies here. Although the Depomed-Lupin agreement concerns a different patent in a different litigation, the negotiations, forecasts and analyses underlying this agreement, and the similar agreements outlined above, are likewise relevant and should be disclosed.

Other courts have likewise compelled production of the underlying negotiations and communications concerning settlement agreements because they are "a valid consideration in determining whether the settlement agreements themselves accurately reflect the patents' value." *Charles E. Hill & Associates, Inc. v. ABT Electronics, Inc.*, 854 F.Supp.2d 427, 430 (E.D.Tex. Apr. 4, 2012); *see also MSTG, Inc., v. AT&T Mobility LLC*, 2011 WL 841437, at *3 (N.D.Ill. Mar. 8, 2011) ("[d]ocuments related to negotiations could shed light on why the parties reached their royalty agreement and could provide guidance on whether some or all of the licenses could be considered a basis for calculating a reasonable royalty."), *aff'd* 675 F.3d at 1348 (Fed. Cir. 2012). The same reasoning applies here, for all of the above reasons.

Further, to the extent that Lupin argues that negotiation documents and communications between parties are no more relevant in the context of the above agreements than in the context of the Lupin-Mylan agreement (Lupin's Resp. to Request No. 89), that objection is misplaced. First, the Court agreed that the Lupin-Mylan agreement and "Lupin's analysis regarding the potential sale of the ANDA to Mylan" were relevant, and ordered Lupin to produce them.[1] Lupin's forecasts and analyses relating to each of the above agreements are equally relevant and should be produced. Second, the argument raised by Lupin's expert Dr. Hoffman that ANDA transfer agreements are not license agreements[2] does not apply here. Shionogi seeks patent license agreements within tailored categories. Each was the result of negotiations concerning comparable patents or technologies, and each reflects a valuation of those patents or technologies. Further, negotiations underlying these agreements are informative on the comparability of other agreements, the structure of comparable agreements, and where relevant, the extent to which the value of the patents or technologies was influenced by litigation. *See Automated Merchandising Sys. Inc. v. Crane Co.*, 279 F.R.D. 366, 370-73 (N.D.W. Va. Oct. 21, 2011) (compelling production of, *inter alia*, "[a]ll documents comprising, concerning and/or relating to" plaintiff's licensing of its own or third-party patents, and "[a]ll documents that bear upon or relate to the issue of what would constitute a reasonable royalty for a license voluntarily taken by [plaintiff] under the [patents in issue].").

* * * *

In short, Lupin's objections to producing the requested documents on relevance or admissibility grounds are without merit. Shionogi respectfully requests that the Court order Lupin to produce all documents and communications in its possession, custody or control that are responsive to Shionogi's Document Request Nos. 88 and 89, as outlined in the above given categories.

[1] August 27, 2012 Order at 13 (D.I. 545).

[2] Declaration of Ivan T. Hofmann at ¶¶ 30-32.

Respectfully submitted,

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)

cc: All Counsel of Record

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